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Azithromycin - An Antibiotic

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Abstract: *Azithromycin is a macrolide antibiotic which inhibits bacterial protein synthesis, quorum-sensing and reduces the formation of biofilm. Accumulating effectively in cells, particularly phagocytes, it is delivered in high concentrations to sites of infection, as reflected in rapid plasma clearance and extensive tissue distribution. Azithromycin is indicated for respiratory, urogenital, dermal and other bacterial infections, and exerts immunomodulatory effects in chronic inflammatory disorders, including diffuse panbronchiolitis, post-transplant bronchiolitis and rosacea. Modulation of host responses facilitates its long-term therapeutic benefit in cystic fibrosis, non-cystic fibrosis bronchiectasis, exacerbations of chronic obstructive pulmonary disease (COPD) and non-eosinophilic asthma.Delayed inhibitory effects on cell function and high lysosomal accumulation accompany disruption of protein and intracellular lipid transport, regulation of surface receptor expression, of macrophage phenotype and autophagy. These later changes underlie many immunomodulatory effects of azithromycin, contributing to resolution of acute infections and reduction of exacerbations in chronic airway diseases. A sub-group of post-transplant bronchiolitis patients appears to be sensitive to azithromycin, as may be patients with severe sepsis. Other promising indications include chronic prostatitis and periodontitis, but weak activity in malaria is unlikely to prove crucial. Long-term administration of azithromycin must be balanced against the potential for increased bacterial resistance. Azithromycin has a very good record of safety, but recent reports indicate rare cases of cardiac torsades des pointes in patients at risk. Azithromycin is a broad-spectrum macrolide antibiotic with a long half-life and excellent tissue penetration.It is primarily used for the treatment of respiratory, enteric and genitourinary infections and may be used in preference to other macrolides for some sexually transmitted and enteric infections. Azithromycin has additional immunomodulatory effects and has been used in chronic respiratory inflammatory diseases for this purpose.Potential major adverse effects include cardiovascular arrhythmias and hearing loss. Macrolide resistance is also a problem, as are interactions with commonly prescribed drugs. Azithromycin, an antibiotic with potential antiviral and anti-inflammatory properties, has been used to treat COVID-19, but evidence from community randomised trials is lacking. We aimed to assess the effectiveness of azithromycin to treat suspected COVID-19 among people in the community who had an increased risk of complications.*

Keywords: Azithromycin; Clinical efficacy; Immunomodulation; Macrolide antibiotic; Mechanisms of action; Pharmacokinetics

I. INTRODUCTION

Azithromycin is a broad-spectrum macrolide antibiotic with bacteriostatic activity against many Gram-positive and Gram-negative bacteria including *Bordetella pertussis* and *Legionella* species. It also has activity against *Mycoplasma pneumoniae*, *Treponema pallidum*, *Chlamydia* species and *Mycobacterium avium* complex. [1]

Information :-

Azithromycin, sold under the brand names **Zithromax** (in oral form) and **Azasite** (as an eye drop), is an antibiotic medication used for the treatment of a number of bacterial infections.[4] This includes middle ear infections, strep throat, pneumonia, traveler's diarrhea, and certain other intestinal infections.[4] Along with other medications, it may also be used for malaria.[4] It can be taken by mouth or intravenously. [2]

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The oral tablet is available as a generic drug as well as the brand-name drug **Zithromax**. Generic drugs usually cost less than the brand-name version. In some cases, they may not be available in all strengths or forms as the brand-name drug. [3]

Azithromycin, a second generation macrolide, broad-spectrum antibacterial, has received increasing attention in recent years because of additional effects on host-defence reactions and chronic human diseases. It is the prototype 15-membered lactone ring azalide, synthesized in the early 1980s as a semi-synthetic derivative of erythromycin. Discovered around the same time by researchers at Pfizer in the United States (Bright & Hauske, 1984) and at PLIVA, Croatia (Kobrehel et al., 1982), PLIVA patented first and licensed the compound to Pfizer. With much improved pharmacokinetic properties over erythromycin, azithromycin became the most widely used broad-spectrum antibacterial in North America. Pfizer Inc's Arthur E. Girard and Gene Michael Bright, together with PLIVA's Slobodan Djokic (posthumously) and Gabrijela Kobrehel, received in 2000 the American Chemical Society's award of “Heroes of Chemistry who have promoted human welfare in the area of health” for their discovery of Zithromax® (azithromycin). [4]

Azithromycin is subsequently slowly released, reflecting its long terminal phase elimination half-life relative to that of erythromycin. These factors allow for a single dose or single daily dose regimen in most infections, with the potential for increased compliance among outpatients where a more frequent antimicrobial regimen might traditionally be indicated. The potential disadvantage of low azithromycin serum concentrations, however, is that breakthrough bacteraemia may occur in patients who are severely ill; nevertheless, animal studies suggest that tissue concentrations of azithromycin are more important than those in serum when treating respiratory and other infections. [5]

Structure of Azithromycin:

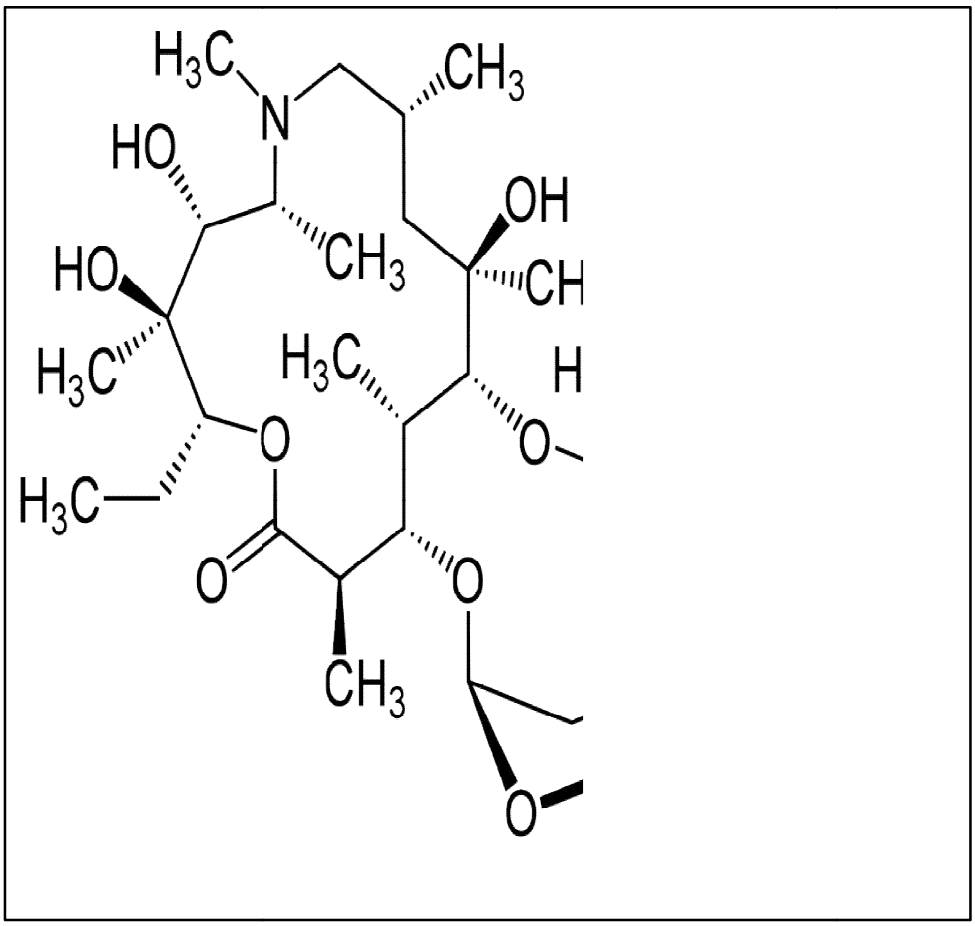

Fig.1 9-deoxy-9α-aza-9α-methyl-9α-homoerythromycin [6]

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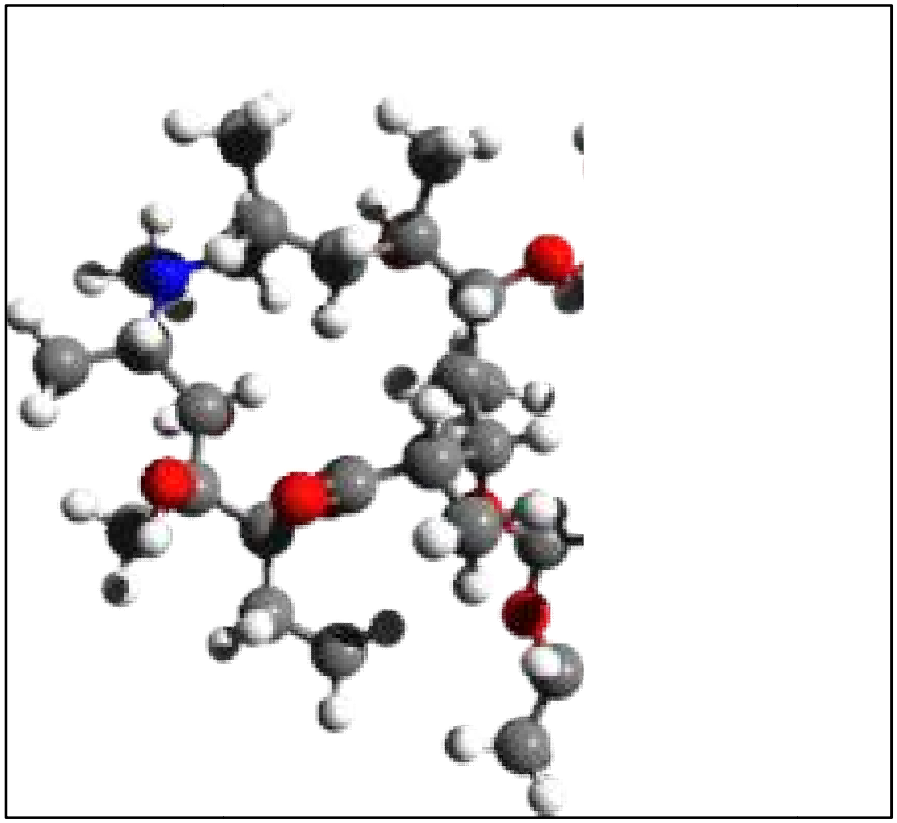

Fig.2 3D structure of Azithromycin[6]

Trade name :-

Azee 500 (cipla)
Arithro 250 (kaybros mwdicament pvt. Ltd.)
Azithral 500 (Alembic)
Zithromax 500 (pfizer)
Azitus 500 (zuventus)+ Azicen 500 (centurion)

IUPAC Formula of Azithromycin :-

2*R*,3*S*,4*R*,5*R*,8*R*,10*R*,11*R*,12*S*,13*S*,14*R*)-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-heptamethyl-15-oxo-11-{[3,4,6-trideoxy-3-(dimethylamino)-β-D-*xylo*-hexopyranosyl]oxy}-1-oxa-6-azacyclopentadec-13-yl 2,6-dideoxy-3*C*-methyl-3-*O*-methyl-α-L-*ribo*-hexopyranoside [14]

Chemical Formula :-

$C_{38}H_{72}N_2O_{12}$

Other Name :-

I] 1Oxa-6-azacyclopentadecan-15-one, 13-[(2,6-dideoxy-3-*C*-methyl-3-*O*-methyl-α-L-*ribo*-hexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-heptamethyl-11-[[3,4,6-trideoxy-3-(dimethylamino)-β-D-*xylo*-hexopyranosyl]oxy]-, (2*R*,3*S*,4*R*,5*R*,8*R*,10*R*,11*R*,12*S*,13*S*,14*R*)-2

II] 1-Oxa-6-azacyclopentadecan-15-one, 13-[(2,6-dideoxy-3-*C*-methyl-3-*O*-methyl-α-L-*ribo*-hexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-heptamethyl-11-[[3,4,6-trideoxy-3-(dimethylamino)-β-D-*xylo*-hexopyranosyl]oxy]-, [2*R*-(2*R**,3*S**,4*R**,5*R**,8*R**,10*R**,11*R**,12*S**,13*S**,14*R**)]-

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III] (2*R*,3*S*,4*R*,5*R*,8*R*,10*R*,11*R*,12*S*,13*S*,14*R*)-13-[(2,6-Dideoxy-3-*C*-methyl-3-*O*-methyl-α-L-*ribo*-hexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-heptamethyl-11-[[3,4,6-trideoxy-3-(dimethylamino)-β-D-*xylo*-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one

Clinical Data :-

Bioavailability :-

The bioavailability of azithromycin is approximately 37%. Concomitant administration of oral azithromycin with food significantly decreases by 50% drug bioavailability. Following a single oral 500 mg dose, peak plasma concentrations of about 0.35-0.45 mg/l are attained within approximately 2 hours. [10]

Pharmacokinetics of Azithromycin :-

Pharmacokinetic is the process of movement of an drug throughout the the body which is characterised by ADME i.e. Absorption, Distribution, Metabolism and Excretion. It also shows what drug does to the body.

The usefulness of erythromycin is limited by its poor pharmacokinetic profile which is characterised by low blood levels and poor gastric acid stability. Erythromycin's short half-life means that a four-times daily dosage schedule is required for effective treatment. In comparison, the azalide structure of azithromycin confers a much improved pharmacokinetic profile. [11]

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Elimination half life of azithromycin :-

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ADME of Azithromycin (Absorption, Distribution, Metabolism and Excretion) :-

Early pharmacokinetic (PK) studies on azithromycin, indicating low plasma levels, were incorrectly interpreted as reflecting poor PK properties. Azithromycin is now known to have a large volume of distribution, achieving high tissue concentrations and is efficiently delivered to sites of infection. Compared with older generation macrolides, it is more stable in acidic media and has a longer half-life, allowing for once a day or even single dose treatment[13]

Medicinal Use :-

Azithromycin is an antimicrobial medication used to treat and manage bacterial infections, including community-acquired community-acquired pneumonia specific respiratory infections, including pertussis and legionellosis sexually transmitted infections such as orchitis, pelvic inflammatory disease, chancroid and granuloma inguinale9 bacterial enteritis due to *Campylobacter* and *Salmonella* species, cholera and travellers' diarrhoea, as well as enteric fever (caused by *Salmonella enterica* serovar Typhi and *S. enterica* serovar Paratyphi).

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Other recommended uses of azithromycin include treatment of severe infection or persistent lymphadenopathy due to *Bartonella henselae* (cat-scratch disease), and some tick-borne infections such as Australian tick typhus or scrub typhus. It is also used as part of combination therapy for *M. avium* complex infections.[15]
Azithromycin, an antibiotic with potential antiviral and anti-inflammatory properties, has been used to treat COVID-19, but evidence from community randomize trials is lacking. We aimed to assess the effectiveness of azithromycin to treat suspected COVID-19 among people in the community who had an increased risk of complications.[16]

Contraindication :-
You should not use azithromycin if you have ever had jaundice or liver problems when you have previously taken this medicine
You should not use azithromycin if you are allergic to it, or if:you have ever had jaundice or liver problems caused by taking azithromycin;
you are allergic to similar drugs such as clarithromycin, erythromycin, or telithromycin.
To make sure azithromycin is safe for you, tell your doctor if you have ever had: Liver disease, kidney disease, myasthenia gravis, a heart rhythm disorder;low levels of potassium in your blood or long QT syndrome (in you or a family member). [17]
This medicine is not expected to harm an unborn baby. Tell your doctor if you are pregnant or plan to become pregnant. It is not known whether azithromycin passes into breast milk or if it could harm a nursing baby. Tell your doctor if you are breast-feeding a baby. [17]

Adverse Effect :-
Azithromycin is generally regarded as a safe antimicrobial agent, and only a few patients discontinue azithromycin due to adverse effects.It is also considered to be safer and with fewer cardiac adverse effects than other macrolides (i.e., erythromycin and clarithromycin).
Azithromycin, like other macrolides, can cause QTc prolongation and has been associated with torsades de pointes and polymorphic ventricular tachycardia. In a large retrospective cohort study, azithromycin use correlated with a small but significant absolute increase in cardiovascular death as well as an increased risk of cardiovascular death relative to amoxicillin. These results were most pronounced among those patients with the highest baseline cardiovascular risk. However, another large cohort study failed to detect an increased risk of death from cardiovascular causes in a population of young and middle-aged adults.[18]
Azithromycin-induced liver injury occurs within 1–3 weeks after azithromycin initiation and is predominantly hepatocellular in nature. Although most patients recover fully, severe cutaneous reactions, chronic injury, and serious complications leading to death or liver transplantation can occur. [19]
This medicine may increase the risk of serious heart or blood vessel problems. Call your doctor right away if you have blurred vision, chest pain, confusion, lightheadedness, dizziness, fainting, fast or irregular heartbeat, trouble breathing, or unusual tiredness or weakness. [20]
Most of the side effects that led people to stop taking the drug were gastrointestinal, such as:[21]
nausea
vomiting
diarrhea
pain in the abdomen
Less common side effects, occurring in up to 1% of cases, include:[21]
heart palpitations or chest pain
acid reflux
dizziness
headache
fatigue
vaginitis
a rash

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dry skin
sun sensitivity[21]

Drug Interaction :-

Azithromycin, generally appear to be free of drug interactions. Caution is advised, nevertheless, when using azithromycin in conjunction with drugs known to interact with erythromycin

Giving azithromycin with antacids containing aluminum or magnesium salts can reduce the rate, but not the extent, of its absorption; azithromycin should be given at least 1 h before or 2 h after the antacid.

Azithromycin serum concentrations are markedly increased when it is given with nelfinavir.

Azithromycin capsules should not be administered with food because it will result in reduced absorption.

Azithromycin possibly enhances anticoagulant effect of coumarins.

Azithromycin possibly increases plasma concentration of theophylline. [22]

Pharmacology :-

Pharmacology of an Azithromycin include it's pharmacokinetics, pharmacodynamics along with the mechanism of action

Mchanism of action :-

In order to replicate, bacteria require a specific process of protein synthesis, enabled by ribosomal proteins. Azithromycin binds to the 23S rRNA of the bacterial 50S ribosomal subunit. It stops bacterial protein synthesis by inhibiting the transpeptidation/translocation step of protein synthesis and by inhibiting the assembly of the 50S ribosomal subunit. This results in the control of various bacterial infections. The strong affinity of macrolides, including azithromycin, for bacterial ribosomes, is consistent with their broad-spectrum antibacterial activities. [23]

Pharmacodynamics :-

Macrolides stop bacterial growth by inhibiting protein synthesis and translation, treating bacterial infections . Azithromycin has additional immunomodulatory effects and has been used in chronic respiratory inflammatory diseases for this purpose.[23]

Therapeutic Activity

Azithromycin in chonic Fatigue syndrome :-

Azithromycin is an antibiotic with immunomodulatory effects. This antibiotic has been successfully used during periods of six months of more in other chronic diseases .The side-effects are known for long term use and mainly limited to gastro-intestinal cramps. The chances for resistance limit its use to individual patients under close supervision. The drug is relatively inexpensive and extensive laboratory tests for side effects are not necessary. The result of a study in 10 CFS patients during 1 to 2 months was positive. We studied the medical records of CFS patients for clinical and laboratory data related to the outcome of the treatment with azithromycin. [7]

Azithromycin in COVID-19 :-

Azithromycin has rapidly been adopted as a repurposed drug for the treatment of COVID-19, despite the lack of high-quality evidence. In this review, we critically appraise the current pharmacological, preclinical and clinical data of azithromycin for treating COVID-19. Interest in azithromycin has been fuelled by favourable treatment outcomes in other viral pneumonias, a documented antiviral effect on SARS-CoV-2 in vitro and uncontrolled case series early in the pandemic. Its antiviral effects presumably result from interfering with receptor mediated binding, viral lysosomal escape, intracellular cell-signalling pathways and enhancing type I and III interferon expression. Its immunomodulatory effects may mitigate excessive inflammation and benefit tissue repair. Currently, in vivo reports on azithromycin in COVID-19 are conflicting and do not endorse its widespread use outside of clinical trials. They are, however, mostly retrospective and therefore inherently biased. The effect size of azithromycin may depend on when it is started. Also, extended follow-up is needed to assess benefits in the recovery phase. Safety data warrant monitoring of drug–drug interactions and subsequent cardiac adverse events, especially with hydroxychloroquine. More prospective data of large

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randomised controlled studies are expected and much-needed. Uniform reporting of results should be strongly encouraged to facilitate data pooling with the many ongoing initiatives. [8]

Azithromycin as an Antiviral :-

Macrolides include erythromycin (EM), azithromycin (AM) and the ketomacrolide telithromycin (Tel). They have well-established antibacterial and anti-inflammatory effects, and preliminary evidence showed that they may also have antiviral effects . The antibacterial action of macrolides is through inhibition of protein synthesis *via* binding to the 50S subunit of bacterial ribosomes. [9]

Medicinal Use :-

Azithromycin is an antimicrobial medication used to treat and manage bacterial infections, including community-acquired pneumonia and sexually transmitted diseases. [14]

community-acquired pneumonia

specific respiratory infections, including pertussis and legionellosis

sexually transmitted infections such as orchitis, pelvic inflammatory disease, chancroid and granuloma inguinale9

bacterial enteritis due to *Campylobacter* and *Salmonella* species, cholera and travellers' diarrhoea, as well as enteric fever (caused by *Salmonella enterica* serovar Typhi and *S. enterica* serovar Paratyphi).

Other recommended uses of azithromycin include treatment of severe infection or persistent lymphadenopathy due to *Bartonella henselae* (cat-scratch disease), and some tick-borne infections such as Australian tick typhus or scrub typhus. It is also used as part of combination therapy for *M. avium* complex infections.[15]

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History of Azithromycin :-

Azithromycin was discovered in 1980 by the Yugoslav pharmaceutical company Pliva and approved for medical use under the brand name Sumamed in 1988. It is on the World Health Organization's List of Essential Medicines. The

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World Health Organization classifies it as critically important for human medicine. In 2010, azithromycin was the most prescribed antibiotic for outpatients in the US, whereas in Sweden, where outpatient antibiotic use is a third as prevalent, macrolides are only on 3% of prescriptions.In 2017, azithromycin was the second most prescribed antibiotic for outpatients in the United States[24]

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